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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,021	02/26/2004	Kristin Feeley	01194-514001 / 03-317	2923

26161 7590 07/25/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
3763	
MAIL DATE	DELIVERY MODE
07/25/2008	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/786,021
Filing Date: February 26, 2004
Appellant(s): FEELEY ET AL.

Kristin Feeley et al.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 05/07/2008 appealing from the Office action mailed 08/01/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

USPN 3,595,230	SUYOEKA	7-1971
US 2003/0175323	UTTERBERG et al.	9-2003
US 2003/0212373	HALL et al.	11-2003

USPN 6,726,658 HOCHMAN 4-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4,12 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suyeoka et al (USPN 3,595,230) in view of Utterberg et al (USPubN 2003/0175323) in further view of Hall et al (USPubN 2003/0212373).

Regarding claims 1-2, 12 and 18-19, Suyeoka discloses an intervention device rod (6); a hub (10) with an extension arm (8) and a delivery tube (2). The delivery tube has a longitudinal partition with a hub opening (see figure 3).

Suyeoka meets the claim limitations as described above but fails to include the rod being an antimicrobial bearing device.

Regarding claims 1-4, 12 and 18-19, Utterberg discloses a catheter/rod that includes iodine. The iodinized catheter/rod is designed with the antimicrobial treatment in order to reduce problems with infection (see paragraph 0002).

At the time of the invention, it would have been obvious to incorporate the teaching of a antimicrobial iodine into the invention of Suyeoka. Both devices are

analogous in the art of percutaneous administration into a patient; therefore, a combination is proper. Additionally, the motivation is provided in that Utterberg teaches an enhanced design and would the device rod to remain sterile during insertion into the patient for reduced infection which is also an ultimate objective of Suyeoka.

Suyeoka meets the claim limitations as described above but fails to include the longitudinal partition being perforated.

Regarding claims 1-4, 12 and 18-19, Hall teaches a shield with a perforated longitudinal partition (see figure 1A #30).

At the time of the invention it would have been obvious to incorporate the perforations of Hall into the invention of Suyeoka. The motivation would have been in order to provide the shield of Suyeoka with enhanced sterility by allowing controlled removal of the sheath due to the perforations which is disclosed as the ultimate objective of the invention. Additionally, Applicant has failed to establish that the perforated slit provides an advantage, is used for a particular purpose or solves a stated problem. Furthermore, one would expect a continuous slit or a perforated slit to perform equally well considering that either slit would enable the rod to be advanced toward a patient and detached from the delivery tube.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Suyeoka et al in view of Hochman (USPN 6,726,658). The modified Suyeoka meets the claim limitations as described above but fails to disclose that the extension arm and the hub have a tapered connection point that enables removal of the extension arm.

Regarding claim 5, Hochman discloses an intervention rod (94), a hub (92), and a delivery tube (12) where longitudinal movement of the hub by a connected extension arm (100,50,80,82 and 84) and finally a clinician (see 52-53) ejects the intervention rod from the delivery tube (12) and detaches the rod from the delivery tube (see figures 1-4). The tube has a continuous slit longitudinal partition (24) and hub opening (32) which allows access to the hub via the exposed portion of extension arm (100). The arm and hub have a tapered connection point (84, 92) that enables removal (see figures 3-4).

At the time of the invention it would have been obvious to incorporate the tapered removal point into the invention of Suyeoka. Both devices are analogous in the art; therefore, a combination is proper. Additionally, the motivation for the incorporation would have been know by one skilled in the art in that removal of the extension arm would allow the hub to be positioned on the patient skin without any rotation prior to positioning.

Claims 14-16 is rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Suyeoka in view of Chang et al (USPN 5,419,766). The modified meets the claim limitations as described above but fails to include the delivery tube being made from polyester.

Regarding claims 14-16, Chang discloses polyester sheaths. The material is used for its hydrophobic property to prevent moisture from traveling through the sheath (see 7:35-62).

At the time of the invention, it would have been obvious to incorporate the material, i.e. polyester, as taught by Chang to make the delivery tube of the modified

Suyeoka. The devices are analogous in the art of percutaneous administration; therefore, a combination is proper. Additionally, the motivation is provided by Chang in that the material prevents moisture from traveling through the sheath. One skilled in the art would reasonably conclude that by preventing the transmission of moisture through the tube one would enhance the sterility of the device prior to use thereby enhancing the safety to the patient.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Suyeoka et al (USPN 3,595,230).

Suyeoka meets the claim limitations as described above but fails to disclose a valve coupled to an open end of the delivery tube.

Regarding claim 17, at the time of the invention, it would have been obvious by one skilled in the art to incorporate a valve, such as a hemostatic valve into the invention of the modified Suyeoka. Hemostatic valves are well known in the medical device arts and are provided in order to prevent fluid leakage and maintain sterility. One skilled in the art would reasonably include a hemostatic valve in order to maintain sterility of the internal components which is an objective of Suyeoka.

(10) Response to Argument

Appellant's first argument is directed to the rejection under 35 U.S.C. 103(a) as being unpatentable Suyeoka (USPN3,595,230) in view of Utterberg (US2003/0175323). Suyeoka does not disclose **"...an antimicrobial agent bearing-bearing device..."**, this teaching is supplied by the Utterberg reference.

Appellant argues that it would have not been obvious to one skilled in the art to modify Suyeoka to incorporate an antimicrobial agent-bearing intervention device.

It is Examiner's position that combination of Suyeoka and Utterberg does disclose an "...an antimicrobial agent bearing-bearing device...". Examiner asserts that main objective of the Suyeoka reference is to maintain sterility of the overall device (col 1, ln 30-45) through the use of the designed guide sheath. Applicant's evidence is that the Suyeoka reference already discloses a guide sheath for maintaining sterility thus it is not necessary for additional sterility.

Examiner asserts that it is well known in the medical arts to apply anti-microbial agents to medical devices to prevent and curtail future infections involved with use. The Utterberg reference teaches that it is **well known ([0009-0016]) that needles that are placed through the skin are prone to infection and prior inoculation of the needles (internal and external) prevents infections and prevents surface bacteria being introduced into the patient through the insertion track or from forming within the inserted needle.** Therefore it would have been an obvious modification to Suyeoka to add an anti-microbial agent to the intervention device in order to maintain sterility of the intervention device after being placed into the body or during insertion even though a sheath is already present on the device.

Appellant's second argument is directed towards the rejection under 35 U.S.C. 103(a) as being unpatentable Suyeoka (USPN3,595,230) in view of Utterberg (US2003/0175323) in further view of Hall et al. (US2003/0212373). The modified Suyeoka does not disclose **"...a delivery tube having a perforated longitudinal**

partition with an opening…", this teaching is supplied by the Hall et al reference. Applicant argues that it would have not been obvious to one skilled in the art to modify Suyeoka to incorporate a delivery tube having a perforated longitudinal partition with an opening. It is Examiner's position that combination of the modified Suyeoka and Hall et al. does disclose an "…a delivery tube having a perforated longitudinal partition with an opening…".

Examiner asserts that main objective of the Suyeoka reference is to maintain sterility of the overall device (col 1, ln 30-45) through the use of the designed guide sheath. Appellant's evidence is that the Suyeoka reference discloses a shield that is rigid yet flexible, and the device of Hall et al. is flexible; therefore it would have not been obvious to add the perforations of Hall et al. to the slot of Suyeoka because the intended use of each is based upon the flexibility and torsional loads applied to each.

Examiner asserts that it is well known in the medical arts to have perforated elements in order to effect removal of exterior guiding elements. The Hall et al. reference teaches that it is **well known ([0005-0007]) that guiding elements often include a weakened area in the form of a slit OR weakened area comprising perforated regions to allow for removal or peeling away of the guide element without removal of other elements during the procedure.** The objective of Hall et al. is to provide a guiding sheath that can be peeled away by a perforated slot but yet maintain stability during insertion. Therefore it would have been an obvious modification to Suyeoka to add perforations or substitute the continuous slot of

Suyeoka for the perforated slot of Hall et al. in order to allow for a removal of the sheath but yet maintain the integrity of the sheath during insertion and thus enhancing the sterility of the device which is again the main objective of the Suyeoka reference.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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/Tatyana Zalukaeva/

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